DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 006188/S-025

SUPPLEMENT APPROVAL

Vintage Pharmaceuticals, LLC d/b/a Qualitest Pharmaceuticals
Agent for DAVA Pharmaceuticals, Inc.
Attention: Bernadette Attinger
Director Regulatory Affairs
7 Clarke Drive
Cranbury, NJ 08512

Dear Ms. Attinger:

Please refer to your Supplemental New Drug Application (sNDA) dated April 23, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Propylthiouracil tablets. We acknowledge receipt of your amendments dated July 29 and October 9, 2015.

We also refer to our letter dated March 30, 2015, requesting changes in the labeling be made to the package insert (PI) and Medication Guide (MG) so as to furnish adequate information for the safe and effective use of the drug related to the use of Propylthiouracil in pregnancy.

This sNDA provides for the following revisions to the labeling for Propylthiouracil consistent with our March 30, 2015, supplement request letter.

- Updated Boxed Warning
- Revised **WARNINGS, Liver Toxicity** subsection and the addition of a **Use in Pregnancy** subsection
- Updated **PRECAUTIONS**, **Pregnancy** and **Nursing Mothers** subsections

The sNDA also provides for the following additional revision to the PI:

- Under **REFERENCE**, the number 1 was replaced with a bullet

In addition, S-025 provides for revisions to the MG consistent with our requests conveyed via email on September 29, 2015.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf .

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Linda Galgay, Regulatory Project Manager, at (301) 796-5383.

Sincerely,

{See appended electronic signature page}

Jennifer Rodriguez Pippins, M.D., M.P.H.
Deputy Director for Safety
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Package Insert
Medication Guide

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JENNIFER R PIPPINS
01/15/2016